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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,763	12/22/2000	Kenneth Jacobs	GIN-6046CP	7028

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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 10/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/745,763

Applicant(s)

JACOBS ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 265-267 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 265-267 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 265-267 are pending.

Applicants' amendment filed July 28, 2004 is acknowledged. Applicants' response has been fully considered. Claim 265 has been amended. Therefore, claims 265-267 are examined.

Oath/Declaration

2. The five executed declarations submitted June 18, 2001 is acknowledged, however, the oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because non-initialed and/or non-dated alterations have been made to the name of the inventor Maurice Treacy and to the address of Vikki Spaulding.

Deposit of Biological Material

3. The receipt of the certificate of deposit of bu45_2 clone filed July 28, 2004 is acknowledged.

Objection Withdrawn

4. The previous objection to new matter added to the specification is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 5-6 in the amendment filed July 28, 2004.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

5. The previous rejection of claim 266 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' response at page 8 in the amendment filed July 28, 2004.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 265-267 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. The claims are directed to a polynucleotide comprising SEQ ID NO:35, specific fragments of SEQ ID NO:35 or the nucleotide sequence of a protein coding sequence of clone bu45_2 deposited under accession number ATCC 98369, a polynucleotide encoding a protein comprising SEQ ID NO:36 or a functional fragment thereof, the allelic variant or a species homolog of the polynucleotide, or a polynucleotide that hybridizes under stringent conditions to the polynucleotide (claim 265); a polypeptide comprising SEQ ID NO:36 or a fragment of SEQ ID NO:36, the amino acid sequence encoded by the cDNA insert of clone bu45_2 deposited under accession number ATCC 98369 (claim 266); and a gene corresponding to the cDNA sequence of SEQ ID NO:35 (claim 267). The specification indicates that the invention is related to the novel polynucleotides and the proteins encoded by such polynucleotides (page 5, lines 5-7), and a polynucleotide has been identified as clone "bu45_2", which encodes a secreted or transmembrane protein and the nucleotide sequence of bu45_2 is determined as SEQ ID NO:35 (page 113, lines 2-15). The specification also indicates the nucleotide sequence of bu45_2 was searched against nucleotide sequence databases, which demonstrated at least some similarity with sequences identified as AA041196, AA452391, Q61260, R13864 and R18560; the predicted amino acid sequence for bu45_2 was searched against amino acid databases, which demonstrated at least some similarity to sequences identified as R99416 (aminopeptidase

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precursor of *Aeromonas caviae*); and based on sequence similarity, bu45_2 proteins and each similar peptide may share at least some activity (page 113, lines 18-32). However, the specification does not disclose the sequence similarity between the identified polynucleotide sequences and SEQ ID NO:35, nor indicates the sequence similarity between the identified polypeptide sequences and bu45_2 proteins. Furthermore, the specification has not identified the activity of bu45_2 protein or peptide. Although the specification indicates the polypeptides and the proteins of the invention such as SEQ ID NO:35 and SEQ ID NO:36 are expected to exhibit one or more uses or biological activities, such as polynucleotides can be used for research by expressing recombinant proteins for analysis, characterization or therapeutic use; polypeptides and proteins can be used as nutritional sources or supplements; and proteins may exhibit cytokine, cell proliferation activity, immune stimulating or suppressing activity (pages 173-189), the direct correlation between the biological activity and the claimed polypeptide is not indicated, and the specific uses of the bu45_2 protein and polynucleotide are not demonstrated. For these reasons, the instant invention does not possess a specific and substantial utility or a well-established utility for the claimed polynucleotides and polypeptide, although there is a general utility that is applicable to the broad class of proteins or polynucleotides. The utility is not a substantial utility because it requires further research to identify or reasonably confirm a "real world" context of use. Basic research to characterize the claimed invention, use in an assay to identify modulators of the instant invention, production of antibodies to identify other related proteins or use of polynucleotides to identify other related sequences do not constitute substantial utilities.

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In response, applicants indicate that the claimed invention has at least one specific and substantial utility and a well-established utility based on the sequence's similarity in sequence to a number of known nucleotide sequences and also based on the predicted protein's similarity to known proteins; sequence similarity is found between the sequences of the present invention and sequences with known utility as indicated in the specification and shown in enclosed Blast results, thus, it is expected the claimed invention to share activity with the known proteins (see page 113 in the specification); and as set forth in the utility guidelines published January 5, 2001, a statement of fact made by an applicant in relation to an asserted utility must be treated as true, unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement, and the record reflects no evidence that would counter the applicants' assertions (pages 6-7 of the response).

The response has been considered, however, the argument is not found persuasive because the specification fails to provide the direct correlation between the biological activity and the claimed polypeptide, nor provides the guidance necessary for specific uses of the claimed polynucleotide and polypeptide. Applicants argue that the claimed invention has at least one specific and substantial utility and a well-established utility based on its sequence's similarity to a number of known nucleotide sequences and also based on the predicted protein's similarity to known proteins as indicated in the specification (page 113) and shown in enclosed Blast results. However, it appears that the sequence similarity is based on a comparison between a fragment of SEQ ID NO:35 or SEQ ID NO:36 to a known polynucleotide or peptide, rather than the entire length of SEQ ID NO:35 (1851 nucleotides) or SEQ ID NO:36 (472 amino acid residues). For example, the Blast results indicate that a specific fragment of the polynucleotide

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of SEQ ID NO:35 (e.g., nucleotides 1411-1830; 779-1283; 1409-1800; 125-479; 100-438) has sequence similarity (97% - 99%) to AA041196 (nucleotides 2-423), AA452391 (nucleotides 1-504), Q61260 (nucleotides 1-394), R13864 (nucleotides 1-357) and R18560 (nucleotides 1-348); and the fragment of the polypeptide of SEQ ID NO:36 (residues 270-339) has 37% sequence identity to R99416 (residues 180-257). The low sequence identity between the polypeptide of SEQ ID NO:36 and R99416, and the sequence identity of the fragment of SEQ ID NO:36 to known polynucleotide from the Blast results, and the coding sequence for SEQ ID NO:36 (residues 1-472) being nucleotides 99-1514 of SEQ ID NO:36 (see attached sequence alignment) indicate further research is required to identify the biological activity of the polypeptide of SEQ ID NO:35, and specific use of the claimed polypeptide and polynucleotide. MPEP 2107.01 defines a "substantial utility" as a utility that "defines a 'real world' use" and that "utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities." In this case, further experimentation is required to identify the biological activity of the claimed polypeptide and specific use of the claimed polynucleotide and polypeptide. Thus, this type of utility is not considered a "substantial utility". Therefore, the claimed invention does not meet the utility requirement of 35 U.S.C. § 101. Since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 265-267 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

8. Claims 265 and 266 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 265 and 266 are directed to a polynucleotide of SEQ ID NO:35 or related sequences, and a polypeptide of SEQ ID NO:36 or related sequences. The specification indicates the fragments of the claimed protein are capable of exhibiting biological activity (page 166, lines 8-19), and the fragments can contain a segment preferably 8 or more contiguous amino acids that share at least 75% sequence identity with the such segment of the disclosed protein (page 168, lines 3-14). However, the specification does not disclose a genus of variants for fragments of SEQ ID NO:36, nor specify which fragment of SEQ ID NO:36 is biologically active, what biological activity the fragment has, and which fragment of SEQ ID NO: 35 encodes a biologically active fragment of SEQ ID NO:36. There is no disclosure indicating all the fragments of SEQ ID NO:36 containing residues 231-240 are functional, and the specification has not identified any biologically active fragment of SEQ ID NO:36 or any nucleotide sequence encoding the biologically active fragment of SEQ ID NO:36. Without guidance for structure to

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function/activity, one skilled in the art would not know which region or residue(s) of SEQ ID NO:36 is essential for function/activity and how to identify a functional polypeptide. The lack of a structure to function/activity relationship and the lack of representative species for the biologically active fragment of SEQ ID NO:36, and the nucleotide sequences encoding the biologically active fragment of SEQ ID NO:36 as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

In response, applicants indicate that the specification provides examples of biological activity (see pages 173-195) and identifies at least one specific function of such a fragment (page 166, lines 13-15). Moreover, the specification provides guidance on what constitutes a fragment of the present invention (page 168, lines 3-14). Therefore, a fragment of SEQ ID NO: 36 is sufficiently described in the specification, and a person of ordinary skill in the art would recognize that applicants were in possession of the claimed invention (pages 7-8 of the response).

The response has been considered, however, the argument is not found persuasive because the specification fails to disclose a genus of variants for fragments of SEQ ID NO:36, and to provide direct correlation between the biological activity and the claimed fragment of SEQ ID NO:36. The specification indicates the fragments have certain sequence identity to the claimed polypeptide (page 168, lines 3-14); the claimed polypeptides and polynucleotides “are expected” to exhibit one or more uses or biological activities as indicated at pages 173-195; and the fragment of the polypeptide “may be” fused to carrier molecule such as immunoglobulins to increase the valency of protein binding sites (page 166, lines 13-15), however, the identification

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of specific fragments of SEQ ID NO: 36 is not provided, and the direct correlation between the biological activity and the claimed fragment is not demonstrated, the skilled artisan cannot envision all the contemplated peptides as fragments of SEQ ID NO:36 and their biological activities. Therefore, a skilled artisan would not recognize applicants were in possession of the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 265 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 265 is indefinite as to “having biological activity” in part (j), it is not clear what biological activity is referred to.

In response, applicants indicate such phrase is sufficiently clear to a person of ordinary skill in the art, and that further definition of the phrase is not required. The response has been considered, however, the argument is not persuasive because the specification does not disclose the biological activity of SEQ ID NO:36 or its fragment. The specification only indicates that based on sequence similarity to R99416 (Aminopeptidase precursor of *Aeromonas caviae*), the bu45_2 proteins and each similar protein or peptide may share at least some activity (Page 113, lines 27-30), however, it does not indicate what the “some activity” is.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claims 265 and 266 remain rejected under 35 U.S.C. 102(a) as being anticipated by Jacobs *et al.* (WO 97/39030, October 23, 1997). The priority date for SEQ ID NOs:35 and 36 is March 19, 1998 (application 09/044,466).

Jacobs *et al.* teaches a protein comprising an amino acid sequence of SEQ ID NO:12 (472 amino acids), which has 99.7% sequence identity with SEQ ID NO:36 (see previously attached sequence match; claim 266, parts (b) and (c)), and a polynucleotide encoding a protein comprising SEQ ID NO:12 (see previously attached amino acid sequence against nucleotide sequence; page 4, lines 1-2, 5-6, 26; page 10, lines 3-4; page 12, lines 16-34; claims 265, parts (j) and (k)).

In response, applicants indicate the rejection under 35 U.S.C. §102(a) (see MPEP § 2132) requires the subject matter upon which the rejection is based to be “by others”; applicants further state that the disclosure in Jacobs upon which the § 102(a) rejection is founded is the work of the inventors of Claims 265 and 266. In this instance, a rejection under 35 U.S.C. § 102(a) is improper if the subject matter of Jacobs relied upon in the rejection is the work of same inventive entity as the subject matter of Claims 265 and 266.

The response has been considered, however, the argument is not persuasive because the reference by Jacobs *et al.* (WO 97/39030) does not have the same inventive entity as the instant

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application, and MPEP § 2132 III states the entity needs only differ by one person to be “by others”. Furthermore, applicant has not filed an affidavit to establish the reference is the work of the same inventive entity as the claimed invention (see MPEP § 2132.1). Thus, the rejection maintains.

Conclusion

11. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

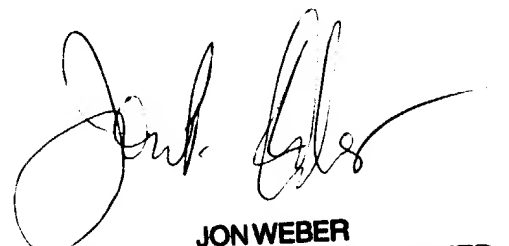
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

CMK
October 8, 2004



JON WEBER
SUPERVISORY PATENT EXAMINER